UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/089,407	07/08/93	LUCIW	P 0035.009

EXAMINER	
WOODWARD	

18N1/0123

ALISA A. HARGIN
CHIRON CORPORATION
INTELLECTUAL PROPERTY DEPARTMENT-R440
4560 HORTON STREET
EMERYVILLE, CA 94608-2916

ART UNIT	PAPER NUMBER
1813	17

DATE MAILED: 01/23/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 10/21/95 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474..
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 60-66 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 1-59 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 60-66 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Applicant's arguments filed October 2, 1995 have been fully considered but they are not deemed to be persuasive.

Claims 60-66 are again rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 60, 61 and 66 recite "synthetic peptide," which leads one to conclude that synthetic is a process limitation. As such it does not impart patentable distinctness to the peptide absent a demonstration that the peptide so produced is materially different either from that recombinantly produced or that which is naturally occurring. Furthermore, the recitation of polypeptides with reference to recombinantly expressed antigens of the envelope region and peptides with respect to synthetically produced antigens is suggestive that a difference exists between the two. Such a difference is nowhere set forth in the specification. Perhaps the intent was to convey a difference in size of the respective products, however, the specification does not set forth ranges for either type of antigen. However, the meaning of "synthetic peptide" could also be inclusive of in vitro translated synthetic mRNA as well as fragments of a protein obtained by chemical or enzymatic means. While the claim language and the specification suggest that recombinantly expressed polypeptides are not within the metes and bounds of "synthetic peptides" neither the claims nor the specification clearly sets forth what is.

The newly inserted phrase "wherein said synthetic polypeptide is prepared by chemical synthesis," does not further clarify the issue as chemical synthesis is involved in any polypeptide synthetic procedure. Moreover, there is no support in the specification for the language employed.

Claims 60-66 are again rejected under 35 U.S.C. § 112, first paragraph, as the specification fails to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

With regard to enablement the Court of Customs and Patent Appeals stated in *In re Cavallito and Gray*, 127 USPQ 203, (CCPA 1960):

> The mere statement of an inventive concept, however, is not a sufficient basis for claiming it. Sufficient information must be given to enable those skilled in the art to practice the invention.

Applicant argues that it would constitute no more than routine experimentation to obtain synthetic polypeptides within the scope of the claims.

For example applicant argues:

> "In addition, one may add the standard immunology text book by Klein (Immunology (John Wiley & Sons, NY, 1982)) particularly at pages 397-407, which presents a formal as well as a practical treatment of various immunological techniques that are usefully applied when experimenting to identify useful antigenic portions of a polypeptide, such as the *env* polypeptide. (page 8, Paper No. 16, October 2, 1995)"

But it would appear that one of skill is being offered the opportunity to experiment to find those synthetic peptides useful in the claimed methods. **The examiner believes that the fact pattern here is akin to that of *In re Gardner*, 166 USPQ 138 (CCPA 1970), particularly the line of reasoning set forth at the lefthand column of page 141.**

The plethora of methods available to make synthetic peptides with the exception of Geysen et al. do not address immunoassays for HIV. With regard to Geysen et al. the examiner cites Webster's Ninth New Collegiate Dictionary:

> **seminal** 2: containing or contributing the seeds of later development: CREATIVE, ORIGINAL.

Thus, Geysen et al. is the first demonstrator of a technology which was to prove extremely useful, however, there is nothing of record to suggest that it would have been regarded as routine experimentation at the time the invention was made.

The sole discussion of synthetic peptides occurs at page 3 of the '501 specification, the '534 specification, the '447 specification and page 5 of the '984 specification it is stated

> "Based on the nucleotide sequences, synthetic peptides may also be prepared."

There is no suggestion therein or elsewhere in the specification as to how to proceed to use said synthetic peptides. In particular, with reference to claim 60, a Jepson claim, there is no disclosure of an assay employing a synthetic peptide nor were any known in the art.

With regard to the Hopp algorithm and the Declaration of Sanchez-Pescador the examiner points out that the algorithm points to areas of a sequence which may be reactive with antibodies, not the same as being immunogenic, but does not direct one as to what peptides should be produced. One is invited to experiment to determine what peptides should be produced for testing.

The examiner has considered the "Expert report of B. Matija Peterlin," but is not persuaded because it is not established that any of the work subsequent to the filing date was performed using the same experimental system as that of applicant's. Exactly what portion of *env* was expressed appears open to question. The point the examiner was making was that the example is directed toward a recombinantly produced polypeptide and offers absolutely no guidance as to how to use a synthetic peptide.

Claims 60-66 are again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,156,949. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the claimed inventions is the manner in which the antigen is produced. However, there has been no showing that the process of producing the antigens in question in anyway leads to a materially or functionally different product.

The specifications of the '501 and '534 applications do not provide support for the invention as is now claimed.

The sole reference to synthetic polypeptides in the '501 and '534 specifications occurs in the summary of the invention section at the close of a paragraph directed to the recombinant expression of polypeptides for use as vaccines. The instant claims are directed to immunoassays employing and solid supports upon are immobilized synthetic peptides from the envelope domain of HIV. Nowhere in the '501 and '534 specifications is reference made to the use of synthetic peptides in immunoassays. On this basis alone the instant claims would be entitled to a filing date no earlier than that of SN 06/773447 which is September 6, 1985.

However, in view of the rejection made under 35 U.S.C. §112, first paragraph above the claims are accorded the filing date of the instant application.

Claims 60-66 are again rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Chang et al. (US Patent 4,774,175). See for example claims 2-15.

Claims 60-66 are again rejected under 35 U.S.C. § 102(b) as being anticipated by Cosand (US Patent 4,629,783). Cosand describes peptides from the env domain of HIV and their use in solid phase immunoassays for the detection of antibodies present in the sera of patients infected with HIV.

Claims 60-66 are again rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Chang et al. (US Patent 4,774,175) for the reasons of record.

Claims 60-66 are again rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Cosand (US Patent 4,629,783) for the reasons of record.

At page 21 (Paper No. 16, October 2, 1995) applicant asserts:

> The cited references, however, disclose examples of diagnostics using particular HIV polypeptide fragments that are predicated on the earlier work of applicants. Any such HIV immunodiagnostic was first invented by applicants who, appropriately, should benefit from their pioneering work by being granted claims that will dominate the patent positions of any such second comers.

Applicant neglects to provide any factual basis for the above assertions. Moreover, there is absolutely no written description of the peptides of the cited references in applicant's '501 and '534 specifications.

NEW GROUNDS OF REJECTION

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

The insertion of **immunogenic** as a modifier of amino acid sequence from the *env* lacks support in the specification as originally filed because there is no guidance as to how to determine which fragments of the *env* domain would be immunogenic other than by trial and error experimentation.

Claims 60-66 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to

an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee of $765 for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MP Woodward whose telephone number is (703) 308-3890. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christine M. Nucker, can be reached on (703) 308-4028.

The fax phone number for this Art Unit is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone

number is (703) 308-0196.

MICHAEL P. WOODWARD
PRIMARY EXAMINER
GROUP 1800

January 21, 1996

5